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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,251	03/04/2002	Kazuya Hosokawa	2462-131US	6081

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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,251

Applicant(s)

HOSOKAWA, KAZUYA

Examiner

Robert B Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 09, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

This office action is in response to amendment filed August 09, 2004. Claims 2-3 are canceled. **Claims 1 and 4-8** as drawn to elected Invention I are currently pending and are under examination.

Priority

The current application filed on February 04, 2002 is a 371 of PCT/JP00/03863 filed on June 14, 2000, which in turn claims priority to foreign application, JP No.11-167453 filed on June 14,1999. A certified translation of foreign application JP No.11-167453 has not been provided.

Withdrawal of Objections and Rejections

The rejection of **claim 7** under 35 U.S.C § 112, first paragraph is withdrawn.

The rejection of **claim 7** under 35 U.S.C § 102(b) as being anticipated by Skogen et al. is withdrawn.

Maintenance of rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was explained in the previous Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Berkner et al. WO 02/15686 (cited in the IDS filed March 21, 2002).

This rejection was explained in the previous Office Action.

Claims 1, 4-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. United Patent 5,679,639.

This rejection was explained in the previous Office Action.

Response to applicant's arguments

The applicants assert that claims 1, 4-6 and 8 have been amended and therefore there is significant structural information respecting the substance within the claims.

In response to the applicants' assertions the examiner would like to state that the applicants have provided new limitations in the claim that do not have adequate written description in the specification of the present application. The applicants state that an active serine residue site of the activated blood coagulation Factor VII, IX and X has been anhydridized, however the applicants do not provide information as to which active

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serine residue is anhydridized. Berkner et al. state that Ser 344 of Factor VII active site has been converted to Ala and therefore providing evidence that they had possession of the invention at the time of filing of their International Application (page 18, example 1). To the contrary, the applicants have simply provided a method that would presumably provide chemically modified blood coagulation Factors VII, IX and X, but have failed to provide any written description of such chemically modified entities.

The applicants further assert that the compound of the '686 publication is formed by the complete substitution of the active site serine of factor VII with alanine and also that the 639 patent does not remotely suggest anhydridizing an active serine residue.

The examiner responds that to the contrary of the applicants assertions, the '686 document teaches that the inhibition of Factor VII active cite may be accomplished by chemical derivatization of the catalytic center by an irreversible chemical inhibitor such as a sulfonyl fluoride (PMSF) (page 7, line 11) and document '639 teaches the chemical derivatization of a functional side group of one or more of the amino acid residues of the polypeptides of the invention, Factor VII, Factor IX or Factor X (column 13, line 20-30).

New rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by anticipated by Suzuki et al. United States Patent 5,939,304.

Suzuki et al. teach a method of anhydridizing activated blood coagulation factors that involve the steps of :

(A) a step of causing the active serine residue site of an activated blood coagulation factor to react with an inhibitor,

(B) a step of performing an alkali treatment at a pH of not less than 11, and

(C) a step of performing an operation of recovery, and carrying out these steps sequentially in the order mentioned, and characterized by causing at least the step of performing the operation of recovery to proceed in the presence of at least one compound selected from the group consisting of polyhydric alcohols and saccharides, and a salt or an amphoteric electrolyte.

The object of this invention is also accomplished by (2) a method according to Item (1) mentioned above, wherein at least one compound selected from the aforementioned group consisting of polyhydric alcohols and saccharides is at least one compound selected from the group consisting of glycerin, ethylene glycol and sucrose (column 3, lines 59-66 and column 4, lines 1-15) (**present claim 7**).

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Thus Suzuki et al. teach all the elements of **claim 7** and these claims are anticipated under 35 USC 102(e).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Nogami et al. (cited in the IDS filed June 20, 2003).

Nogami et al. disclose activated Factor Xa, that has been anhydridized into an inactive form of Factor X, in which dehydroalanine has replaced the active serine. Nogami et al. teach further that the active Factor X molecule was chemically modified with PMSF (Preparation of Anhydro-Fxa, page 31001, column 2)(**present claims 1, 4-6 and 8**). Thus Nogami et al. teach all the elements of **claim 1, 4-6 and 8** and these claims are anticipated under 35 USC 102(a).

Conclusion


No claims are allowed


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B. Mondesi
Patent Examiner
Group 1653
09-30-09


ROBERT A. WAX
PRIMARY EXAMINER